SEP 17 2003

Section 2 - 510(k) Summary and Certification K032495

[As required by 21 CFR 807.92(c)]

1. Submitter's Name / Contact Person

Diane Brinza
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2. General Information

Trade Name	The Lifecore Stage-1 Angled Abutment System consists of the following products: • Regular Diameter (RDS) 15° Cement on Crown (COC) Abutment • Regular Diameter (RDS) 20° COC Abutment • Stage-1 Angled Abutment Screw, .048" Hex, Titanium • Accessories: Stage-1 Angled Abutment Try-Ins
Common / Usual Name	Angled Abutment System
Classification Name	Lifecore Stage-1 Angled Abutment system is a precision attachment system intended for use with a Class III medical device, thereby the Stage-1 Angled Abutment System is considered Class III (per 21 CFR 872.3640).
Identification of Equivalent Devices	• Pre-Angled Post manufactured by Implant Innovations (3i). • ITI Angled Abutment manufactured by Straumann USA. • Stage-1 Abutment System manufactured by Lifecore Biomedical, Inc.

3. Device Description

The Lifecore Stage-1 Angled Abutment System is designed for use with endosseous implants to provide support and retention for single or multi-unit (splinted) cement retained restorations in the mandible or maxilla where angle correction is required. The Stage-1 Angled COC Abutment and Screws will facilitate ideal tooth positioning due to lack of available bone, access limitation, or to correct angulation of implant placement.

The system consists of 15 and 20 degree angled abutments, angled abutment screw, and angled abutment try-ins. One angled abutment is packaged together with an angled abutment screw to allow the clinician to have the components required for clinical use. The angled abutments and angled abutment screw are manufactured from titanium alloy (Ti 6Al-4V E.L.I.) which conforms to ASTM Standard Specification F136.

4. Intended Use

The Lifecore Stage-1 Angled Abutment is intended to attach to an endosseous implant and provide support and retention for single or multi-unit (splinted) cement retained restorations in the mandible or maxilla where angle correction is required.

5. Technological Characteristic Comparisons

The Lifecore Stage-1 Angled Abutment System is substantially equivalent to the Pre-Angled Post manufactured by Implant Innovations (3i), and ITI Angled Abutment manufactured by Straumann USA, and the connection features of the Stage-1 Abutment System, manufactured by Lifecore Biomedical, Inc. Compared to the predicate devices, the Lifecore Stage-1 Angled Abutment System is substantially equivalent in intended use, design, material, and accessories.

6. Summary of Studies / Nonclinical Tests

The Lifecore Stage-1 Angled Abutment System has been subjected to testing to verify design specifications. Test results indicate the Stage-1 Angled Abutment has met the design criteria for static and fatigue loads and is likely to resist corrosion. Dimensional inspections are routinely performed, Electrochemical Corrosion Evaluation of Uncoupled and Coupled Implant and Restorative Alloys has been performed to determine corrosion properties when exposed to artificial saliva and to determine the galvanic corrosion properties of the Precious Alloy/CP titanium and Precious Alloy/Ti-6Al-4V galvanic couples. All have been found to be within acceptable limits.

7. Substantial Equivalence Comparison

The Lifecore Stage-1 Angled Abutment System is substantially equivalent to the following products:

Implant Innovations (3i) Pre-Angled Posts	**Straumann USA ITI Angled Abutments**	**Lifecore Stage-1 Abutments**
Implant Innovations, Inc. 4555 Riverside Dr. Palm Beach Gardens, FL 33410 USA	Straumann USA 1601 Trapelo Road Waltham, MA 02451 USA	Lifecore Biomedical, Inc. 3515 Lyman Blvd. Chaska, MN 55318 USA

8. Conclusion (statement of equivalence)

The data submitted in this 510(k) is in support of substantial equivalency of Lifecore Stage-1 Angled Abutment System to the following commercially marketed devices:

- Implant Innovations (3i) Pre-Angled Posts
- Straumann USA ITI Angled Abutments
- Lifecore Stage-1 Abutments

These current products as defined by their product literature, demonstrate the basis for the substantial equivalency relative to indications, materials, and design. The intended use of these devices is the same as the Lifecore Stage-1 Angled Abutment System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2003

Ms. Diane Brinza
Regulatory Affairs Supervisor
Lifecore Biomedical, Incorporated
3515 Lyman Boulevard
Chaska, Minnesota 55318-3051

Re: K032495
Trade/Device Name: Lifecore Stage-1 Angled Abutment System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: August 11, 2003
Received: August 13, 2003

Dear Ms. Brinza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name:
Lifecore Stage-1 Angled Abutment System

Indications for Use:

The Lifecore Stage-1 Angled Abutment is intended to attach to an endosseous implant and provide support and retention for single or multi-unit (splinted) cement retained restorations in the mandible or maxilla where angle correction is required.

K032495

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)